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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,289	05/31/2002	Vega Massignani	PP01639.102; 2300-1639	6882
7590 08/29/2007 Chiron Corporation Intellectual Property Department R440 PO Box 8097 Emeryville, CA 94662-8097			EXAMINER DEVI, SARVAMANGALA J N	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 08/29/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/031,289

Applicant(s)

MASIGNANI ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 10, 24, 26-28 and 30-32 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) 24 ~~is/are~~ withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 10, 26-28 and 30-32 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Request for Continued Examination

1) A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicants' submission filed on 08/20/07 has been entered.

Applicants' Amendment

2) Acknowledgment is made of Applicants' amendment filed 08/20/07 in response to the final Office Action mailed 02/28/07.

Status of Claims

3) Claims 1, 24 and 26-28 have been amended via the amendment filed 08/20/07.
Claims 7, 9, 13, 15, 17, 19, 21, 23, 25 and 29 has been canceled via the amendment filed 08/20/07.
Claims 1, 10, 24, 26-28 and 30-32 are pending.
Claims 1, 10, 26-28 and 30-32 are under examination.

Prior Citation of Title 35 Sections

4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Rejection(s) Moot

6) The rejection of claims 25 and 29 made in paragraph 10 of the Office Action mailed 02/28/07 under 35 U.S.C. § 112, first paragraph, as containing new matter, is moot in light of Applicants' cancellation of the claims.

7) The rejection of claims 25 and 29 made in paragraph 11 of the Office Action mailed 02/28/07 under 35 U.S.C. § 112, first paragraph, as being non-enabled with regard to the full

scope, is moot in light of Applicants' cancellation of the claims.

Rejection(s) Withdrawn

8) The rejection of claims 1, 10, 25-28 and 30-32 made in paragraph 11 of the Office Action mailed 02/28/07 under 35 U.S.C. § 112, first paragraph, as being non-enabled with regard to the full scope, is withdrawn in light of Applicants' amendment to the base claim.

Rejection(s) Maintained

9) The rejection of claims 1, 10, 26-28 and 30-32 made in paragraph 10 of the Office Action mailed 02/28/07 under 35 U.S.C. § 112, first paragraph, as containing new matter, is maintained for reasons set forth therein and herein below.

Applicants cite MPEP § 2163.02 and contend that the test for written description in a parent application is whether the disclosure of the application relied upon reasonably conveys to one of skill in the art that the inventor had possession at that time of filing of the later claimed subject matter. Applicants submit that written description requires only that the specification convey to those of skill in the art that Applicant at the time of filing the application was in possession of the invention as claimed, not that there be word for word support for the pending claims. Applicants state that MPEP § 2163.02 sets forth that the subject matter of the claim need not be described literally (i.e., using the same terms or in *haec verba*) in order for the disclosure to satisfy the written description requirement. Applicants point to original claim 1 and lines 24-25 of page 1 of the specification and state that the invention provides fragments of the proteins disclosed in international patent application WO99/36544, wherein the fragments comprise at least one antigenic determinant. Applicants state that since SEQ ID NO: 1331 is an amino acid sequence corresponding to a fragment of one of the proteins disclosed in WO99/36544, the recitation of a 'purified polypeptide comprising the amino acid sequence of SEQ ID NO: 1331, wherein the polypeptide comprises at least one antigenic determinant' is clearly supported in the specification. Applicants further submit that lines 28-29 of page 1 indicate that the length is preferably 100 amino acids or less, and therefore there is support for the recitation wherein the polypeptide 'has a length of 100 amino acids or less'. Applicants assert that lines 22-27 of page 3 indicate that the invention provides 'the use of nucleic acid, *protein*, or antibody according to the invention in the manufacture of: (ii) a diagnostic reagent for *detecting the presence* of a

Neisserial bacteria or *of antibodies against Neisserial bacteria*, ... said Neisserial bacteria may be any species or strain (such as *N. gonorrhoeae*) but are preferably *N. meningitidis*, especially strain A or *strain B*' [Emphasis by Applicants]. Applicants further submit that original claim 12 dependent from claim 1, directed to the fragments of the proteins in WO99/36544 (of which SEQ ID NO: 1331 is), includes a similar use of the claimed fragments. With these, Applicants conclude that one of skill in the art would easily recognize that the inventors had possession of the present claims because a polypeptide having the amino acid sequence of SEQ ID NO: 1331 of 100 amino acids or less was a protein of the present invention and that one use of the present invention was to detect the presence of antibodies raised against *Neisseria meningitidis* serogroup B in a sample.

Applicants' arguments have been carefully considered, but are not persuasive. The new matter that was specifically identified in the amended claim 1 via paragraph 10 of the Office Action mailed 02/28/07 included the new limitations: 'and wherein the polypeptide can detect the presence of antibodies raised against *Neisseria meningitidis* serogroup B in a sample'. The parts of the specification and the original claims pointed to by Applicants do not support the limitation 'serogroup B in a sample', i.e., the instantly claimed polypeptide having a length of 100 amino acids or less and comprising the amino acid sequence of SEQ ID NO: 1131 and at least one antigenic determinant which can detect the presence of antibodies raised against '*Neisseria meningitidis* serogroup B in a sample'. The limitation '*N. meningitidis* ... strain B' does not provide support for the limitation '*Neisseria meningitidis* serogroup B' [Emphasis added]. The limitation 'in a sample' lacks literal or non-literal descriptive support. The limitation: the polypeptide can detect the presence of antibodies raised against '*Neisseria meningitidis* serogroup B in a sample' lacks descriptive support in the instant specification as originally filed. Certainly, one of skill in the art would not easily recognize that the inventors had possession of the claimed invention. Contrary to Applicants' assertion, the disclosure of the instant application does not reasonably convey to one of skill in the art that the inventors had possession of the claimed subject matter at the time of the invention. The rejection stands.

Remarks

10) Claims 1, 10, 26-28 and 30-32 stand rejected.

11) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

12) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

13) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

August, 2007


S. DEVI, PH.D.
PRIMARY EXAMINER